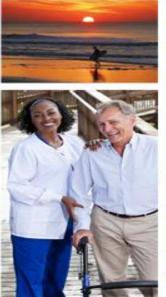


COVID-19 Vaccine Provider Town Hall

9-1-2021









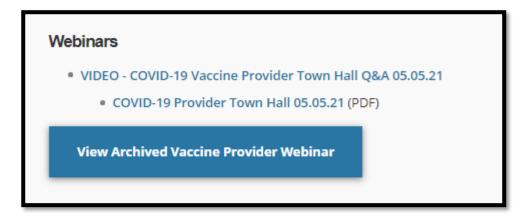








Recorded Town Hall Sessions and Slides Available DHEC's COVID-19 Provider Website





VAMS and DHEC COVID-19 Vaccination Program Updates and Reminders



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	COVII	D-19 Vaccinati	ion Pro	gram Report	ing Reminde	rs		
Requirement Area	System	Metrics						Frequency
Inventory	VAMS	New vaccine deliveries	Doses	ses Administered Waste		Transfers	Same Day	
	VaccineFinder	On-hand inventory					Daily	
	DHEC Provider Portal H3707	No lon	ger a r	eporting r	equiremen	nt as o	of Friday, July 2	2, 2021
	VAMS	Inventory Request with 1 st and 2 nd dose amounts specified in notes						Mondays by 11:59pm
Vaccine Administration	VAMS, or Electronic Medical Record/Electronic Health Record with established interface with SIMON, or Direct data entry into SIMON	Vaccine administration event						Within 24 hours
Temperature Monitoring	Via email to COVIDVaccines@dhec.sc.gov Facility Name in the subject line	Temperatu monitoring logs COVID-19 vac containing stora	for any ccine	temperature	ded continuous monitoring dev reports		COVID-19 Transport Logs	Fridays by 5pm



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VAMS 5.2.2 (August 20, 2021)

Clinic Portal Updates

- Inventory managers and clinic administrators at all clinics can request additional COVID-19 vaccine doses.
- Healthcare professionals at all clinics can bulk upload additional dose past vaccinations.
 - Note: When exporting additional dose appointment data in bulk vaccination upload template, users will select Additional Dose as the COVID-19 dose.
- Healthcare professionals can individually record additional dose past vaccinations.
- Clinic administrators at standard/mobile clinics can send messages to recipients scheduled to receive an additional COVID-19 vaccine dose at their clinic.
 - If no appointments are found that match the parameters, this button will not be available.
- The Vaccination Administration Report and Scheduled Appointment Reports display data relevant to additional doses.
- Clinic administrators at all clinics can remove clinic users from multiple clinics simultaneously.
- Users with the healthcare professional and clinic administrator role can view the time/date a vaccination record was created in addition to the time/date the vaccination was modified.

Additional Updates

- The Prevaccination Questionnaire inquires if any of the following statements are applicable to a recipient
 - Am a male between ages 12 and 29 years old
 - Have a history of myocarditis or pericarditis
 - Have a weakened immune system (I.e., HIV infection, cancer) or take immunosuppressive drugs or therapies
 - History of Guillain-Barré Syndrome (GBS)



VAMS 5.3 (August 27, 2021)

Clinic Portal Updates

- Clinic administrators and inventory managers will be able to log Pfizer-BioNTech vaccine inventory for Unit of Sale (UoS) National Drug Codes (NDCs) ending in 02 and 03
- The Clinic Capacity Report displays the total number of appointments booked for Additional Dose in the Additional Dose Appointment Booked column

Recipient Portal Updates

- QR codes are available to display vaccination certificates
 - Note: When scanned, the QR code will generate a link to an external site that will display the recipient's vaccination details.



Please continue to review the VAMS updates when logging into your VAMS account. These announcements contain the most updated information regarding the system.

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COVID-19 Provider: DHEC Contacts

- Provider Operations: COVID-19 Vaccine Management
 - Vaccine inventory requests, vaccine orders, direct ship vaccine shipments/deliveries, temperature monitoring, transport logs
 - COVIDVaccines@dhec.sc.gov
 - COVID-19 Vaccine Temperature Excursion Reporting <u>Form</u> and Guidance <u>Document</u>
- Provider Operations: COVID-19 Provider Support
 - New enrollment form submissions, vaccine coordinator contact information changes, enrollment form updates, redistribution agreements
 - <u>COVIDProviderEnrollment@dhec.sc.gov</u>

- DHEC Vaccine Location Web <u>Map</u>
 - Red/green color updates, information updates
 - <u>VaxStatus@dhec.sc.gov</u>
- COVID-19 Provider Portal Reporting
 - Inquiries or assistance with DHEC H3707 Provider Portal
 - Vaxreportinghelp@dhec.sc.gov
- Provider Operations: New Provider Onboarding and VAMS
 - Technical assistance, additional clinics, and questions regarding VAMS
 - VAMS@dhec.sc.gov



Please, do <u>NOT</u> submit a SIMON Help Desk Request for any COVID-19 vaccine related issue.



General COVID-19 Vaccination Updates



UPDATED INFORMATION: PFIZER-BIONTECH VACCINE EXPIRATION EXTENSION

- The FDA has approved an amendment to the EUA for Pfizer-BioNTech extending the expiration dates of COVID-19 Vaccine from six to nine months.
- Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine may remain in use for 3 months beyond the expiry date printed on the label as long as authorized storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained. Please note: the ultra-cold temperature range has been broadened to include -90° C (-130°F). Frozen vials stored at -25°C to -15°C and refrigerated vials (2°C to 8°C) are **NOT** eligible for extension.



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For vials with expiration dates in the future, updated expiry dates for Pfizer vaccine maintained in ultra-cold storage are shown below.

Printed	<u>Updated</u>
<u>Expiry</u>	<u>Expiry</u>
Date	Date
August	November
2021	2021
September	December
2021	2021
October	January
2021	2022
November	February
2021	2022
December	March
2021	2022
January	April
2022	2022
February	May
2022	2022



Pfizer Extension, Cont.

In addition, per FDA's concurrence letter to Pfizer-BioNTech, the shelf-life extension from 6 months to 9 months when stored at -90°C to -60°C is also applicable to batches that might have expired prior to the issuance of this concurrence letter provided they have been stored at -90°C to -60°C.



Regulatory Updates (August 23, 2021)

On Monday, August 23, 2021, <u>FDA approved COMIRNATY</u> (<u>COVID-19 Vaccine, mRNA</u>) for use as a two-dose series (<u>provide link</u>) for individuals 16 years of age and older. It can also be used under the EUA to prevent COVID-19 in individuals 12 through 15 years, and provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.



COVID-19 Provider Agreements

- Administration of the product off label may not be covered under the PREP Act or the PREP Act declaration; therefore, providers may not have immunity from claims.
- Individuals who receive an off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event.
- CDC has defined the scope of the CDC COVID-19 Vaccination Program in terms of how the USG-provided vaccines may be used in the program. Providers giving off-label doses would be in violation of the CDC Program provider agreement potentially impacting their ability to remain a provider in the CDC program.
- Administration fees may not be reimbursable by payers.



Interchangeability of FDA authorized and FDA approved COVID-19 Products:

The FDA approved Pfizer-BioNTech product COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under EUA have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under the EUA to administer the vaccination series for those seeking the approved vaccine. The Fact Sheet for Recipients provides additional information about both the approved and authorized vaccine. Providers should continue to use the vaccines on their shelves.



Weekly updates will continue to be posted to the COVID-19 Vaccine Provider Guidance webpage.



ICC South Carolina Department of Health and Environmental Control

CONTACT US

Provider Operations Unit

COVID-19 Vaccine Management : COVIDVaccines@dhec.sc.gov

COVID-19 Provider Support : <u>COVIDProviderEnrollment@dhec.sc.gov</u>

VAMS: VAMS@dhec.sc.gov

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